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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,839	03/01/2000	RAJA G. ACHARI	719-75-PCT/U	4232

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/486,839	ACHARI ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on January 14, 2002 in Paper No. 10 wherein claims 4, 5, 14, 17-18, and 21 have been amended. Currently, claims 1-21 are pending in this application.

Applicant's remarks filed on January 14, 2002 in Paper No. 10 with respect to the objection of claim 21 made under 37 CFR 1.75 (c) for improper dependent for failing to further limit claim 21 of record stated in the Office Action dated June 5, 2001 have been fully considered and are found persuasive. Therefore, this objection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 14, 17-18, and 21 are rejected under 35 U.S.C. 112, second paragraph, for use of the indefinite expression "a chemically modified equivalent" or " chemically modified equivalents" in claims 7, 14, and 21 of record stated in the Office Action dated June 5, 2001.

It is noted that claims 4-5 and 17-18 have been amended to clearly define " said concentration " in the claims.

Applicant's remarks filed on January 14, 2002 in Paper No. 10 with respect to the rejection made under 35 U.S.C. 112 second paragraph for use of the indefinite expression "a chemically modified equivalent" or " chemically modified equivalents" in

claims 7 and 14 have been fully considered but are not persuasive to remove the rejection. Note that "a chemically modified equivalent" of scopolamine or " chemically modified equivalents" of scopolamine may encompass any scopolamine having any possible substituents or functional groups. A skilled artisan would recognize that any significant structural variation to a compound would be reasonably expected to alter its properties. Therefore, the rejection is adhered as to claims 7, 14, 17-18, and 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith in view of Osol et al. for reasons of record stated in the Office Action dated June 5, 2001.

Applicant's remarks filed on January 14, 2002 in Paper No. 10 with respect to this rejection of claims 1-21 made under 35 U.S.C. 103(a) have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art for the following reasons.

Applicant's arguments that "concerning the use of polyvinyl alcohol, gelling agents, bioadhesives, scopolamine salts, thickening agents, and surfactants, the Office

provides no direct suggestion or "compelling motivation" as required by Section 103 to modify the Keith reference to incorporate any of these presently claimed features" are not found persuasive. Keith clearly discloses his aerosol spray nasal composition comprising a major amount of an aerosol spray vehicle (pharmaceutically acceptable carriers) and scopolamine salt such as scopolamine hydrochloride (see page 2 the last paragraph). The instant claimed invention is directed to an intranasal composition comprising scopolamine or scopolamine salts such as scopolamine bromide. Hence, Keith's reference is seen to clearly provide the motivation to modify the spray nasal composition by employing similar aerosol spray vehicle or pharmaceutically acceptable carriers such as polyvinyl alcohol, gelling agents, bioadhesives, thickening agents, and surfactants herein. As discussed in the previous Office Action (June 5, 2001), polyvinyl alcohol, gelling agents, bioadhesives, thickening agents, and surfactants herein are well known pharmaceutically acceptable gelling agents or pharmaceutically acceptable carriers according to Osol et al. Therefore, one of ordinary skill in the art would have been motivated to modify these known pharmaceutically acceptable carriers in the known nasal composition of Keith because the determination of well known pharmaceutical acceptable carriers in the pharmaceutical art to be used in a composition are considered well in the competence level of an ordinary skilled artisan in pharmaceutical science.

Moreover, Keith teaches an aqueous nasal composition comprising scopolamine hydrochloride. Applicant's admission regarding the prior art in the specification herein (page 3, lines 13-19) teaches that intranasal spray scopolamine compositions are

known to be at a pH of 4±0.2. The instant claimed invention is directed to the intranasal spray scopolamine composition herein is at a pH below about 4 or about 3.5, which is considered within or substantially close to the known pH range of the prior art. Further, one of ordinary skill in the art would have been motivated to optimize the concentration of the buffer salt in the aqueous composition in order to maintain the pH because the optimization of the concentration of the buffer salt in an aqueous composition in order to maintain the pH is considered well within the skill of artisan, involving merely routine skill in the art.

Therefore, motivation to combine the teachings of the prior art to make the present invention is seen. The claimed invention is clearly obvious in view of the prior art.

The record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.
Patent Examiner, AU 1617
April 3, 2002

MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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